CNS Drugs

PEER-REVIEWED FEATURE

Efgartigimod Alfa: Adis Evaluation

Clinical Considerations

- First neonatal Fc receptor antagonist for the treatment of gMG
- Effectively reduces disease burden and improves muscle strength and quality of life relative to placebo
- Clinical benefits consistent and reproducible for > 1 year of treatment in an ongoing extension trial
- Generally well tolerated

Plain Language Summary

Background and rationale

- Generalised myasthenia gravis (gMG) is a chronic, autoimmune neuromuscular disorder that can significantly impair quality of life
- Several novel targeted therapeutic approaches have emerged to provide faster onset of action compared with conventional immunosuppressive therapy, favourable tolerability profile and the potential for a sustained disease control for patients with gMG
- Intravenous efgartigimod alfa (also known as efgartigimod alfa-fcab in the USA; Vyvgart®) is the first neonatal Fc receptor antagonist approved in several countries worldwide, including the USA and EU for the treatment of gMG in adults who are anti-acetylcholine receptor (AChR) antibody positive, and in Japan for the treatment of gMG regardless of antibody status

Clinical findings

- In the pivotal clinical trial in patients with gMG, efgartigimod alfa rapidly reduced disease burden and improved muscle strength and quality of life The beneficial effects of efgartigimod alfa occurred early and were durable and reproducible. Longer term, efgartigimod alfa provided consistent clinically meaningful improvements in patients with gMG
- Efgartigimod alfa is generally well tolerated, with most adverse events being mild to moderate in severity

Conclusion

Efgartigimod alfa is a novel, effective and generally well-tolerated treatment option for adults with gMG